JAN 1 2 2005

K043422

510(k) Summary of Safety and Effectiveness

Date Prepared:	November 8, 2004
Submitted:	Asahi Intecc Co., Ltd.
	1703 Wakita-cho, Moriyama-ku, Nagoya,
	Aichi, 463-0024, Japan
Contact Person:	Yoshi Terai
	Director of Asahi Intecc US Office
Address:	1301 Dove St. Suite 350 Newport Beach, CA 92660
Phone Number:	Phone : (949)756-8252
Fax Number:	Fax : (949)756-8165
Device Trade Name:	Asahi Wire Asahi PTCA Guide Wire, J Shape series
Classification Name:	Catheter Guide Wire, Class II (21 CFR 870.1330)
Predicate Device:	JoWire Neo's PTCA Guide Wire K022762
	JoWire Asahi PTCA Guide Wire K031277
	Asahi Wire Asahi PTCA Guide Wire K032615
	Asahi Wire Asahi PTCA Guide Wire Confianza Pro K041531

Device Description:

The Asahi PTCA Guide Wire, J Shape series is steerable guide wire with a maximum diameter of 0.014" and available in 180 cm and 300 cm length. The extension wire is connected to the end of the guide wire outside the body. The wire is constructed from a stainless steel core wire with varying core lengths and diameter for each design. The core wire and coil are soldered, for some items welding is used for tip parts instead of soldering. The distal end of the guide wire has a radiopaque tip that is available as a pre shaped "J" and is made soft to easily bend with the vessel curve. The coating (hydrophilic and silicone) is applied to the distal portion of the wire guide wire. The proximal section of the guide wire is coated with PTFE. H on the product code indicates hydrophilic coating, and J indicates pre shaped "J" tip of the guide wire.

Intended Use:

The Asahi PTCA Guide wire, J Shape series is intended to facilitate the placement of balloon dilatation Catheter during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA). The Asahi PTCA Guide wire, J Shape series is not to be used in the cerebral blood vessel

Device Technological Characteristics and Comparison to Predicate Device:

The Asahi PTCA Guide Wire, J Shape series is made of the same materials, available in the same diameters and lengths, have the same design and indications for use as the predicate devices and other currently marketed PTCA Guide Wires.

Performance Data:
Bench and biocompatibility testing were conducted according to the recommendations from relevant FDA guidance to demonstrate that the Asahi PTCA Guide Wire, J Shape series met the acceptance criteria and performed similarly to the predicate devices. No new safety or effectiveness issues were raised during the testing.

Conclusion:
The Asahi PTCA Guide Wire, J Shape series is substantially equivalent to the claimed predicates devices and other currently marketed PTCA Guide Wires.

K043422

Premarket Notification [510(k)] Number

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 12 2005

Mr. Yoshi Terai
Director
Asahi Intecc US Office
1301 Dove St., Suite 350
Newport Beach, CA 92660

Re: K043422
Trade/Device Name: Asahi PTCA Guide Wire, J Shape Series
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: II
Product Code: DQX
Dated: December 3, 2004
Received: December 13, 2004

Dear Mr. Terai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Vochmer

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K043422

Device Name: Asahi PTCA Guide Wire, J Shape series

Indications For Use:

To facilitate the placement of ballon dilation Catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA). The Asahi PTCA Guide Wire, J Shape series is not to be used in the cerebral vasculature.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Lachman

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K043422